Appendix B

Additional Agreement Terms and Conditions

1. SUBSTANTIAL GOVERNMENT INVOLVEMENT

In accordance with the Statement of Work, the Government will play a major role in the cooperative agreement including, but not limited to, the identification of requirements, the review of proposals and the participation in review/evaluation panels. In addition the Government will conduct regular program reviews and will report to the program sponsor.

2. PROTECTION OF HUMAN SUBJECTS

By signing this agreement or accepting funds under this agreement, the Recipient assures that it will comply with applicable provisions of the following national policies for human subjects: (a) DoD Directive 3216.2, (b) 32 CFR Part 219, (c) 45 CFR Part 46 (d) 10 US Code 980, (e) SECNAVINST 3900.39D, (f) SSCPACINST 3900.10E, (g) NIH Guidelines and all other applicable regulatory compliance in effect at the time funds are to be utilized for human subject research.

The Recipient shall provide the government with copies of the following documents prior to performing any efforts that involve human subjects:

1. An appropriate institutional assurance. The institutional assurance may be a DoD/Navy or Federal Wide Assurance (FWA). If the assurance is not a Navy assurance, the institution must also hold a Navy Addendum, a copy of which shall be submitted to the government.
2. Documentation of the Institutional Review Board's (IRB) initial and continuing review and approval.
3. IRB-approved informed consent form, except when not required consistent with law and regulation.
4. IRB-approved research protocol.
5. Documentation of completed research ethics and human subject protections training by the principal investigator.
6. Notification of efforts that involve DoD subjects.

The Recipient shall include this clause in all Subawards.

3. PROTECTION OF ANIMALS

By signing this agreement or accepting funds under this agreement, the Recipient assures that it will comply with applicable provisions of the following national policies concerning animals: (a) Rules on animal acquisition, transport, care, handling, and use in 9 CFR Parts 1-4, Department of Agriculture Rules implementing the Laboratory Animal Welfare Act of 1966 (7 U.S.C. 2131-2156), and guidelines in the national Academy of

Sciences (NAS) “Guide for the Care and Use of Laboratory Animals” (1996), including the Public Health Service Policy and Government Principles Regarding the Care and Use of Animals in Appendix D to the guide, (b) Prohibitions on the purchase or use of dogs or cats for certain medical training purposes, in Section 8019 (10 U.S.C. 2241 note) of the Department of Defense Appropriations Act, 1991 (Pub. Law 101-511), (c) Rules of the Departments of Interior (50 CFR Parts 10-24) and Commerce (50 CFR Parts 217-227) implementing laws and conventions on the taking, possession, transport, purchase, sale, export, or import of wildlife and plants, including the Endangered Species Act of 1973 (16 U.S.C. 1531-1543), Marine Mammal Protection Act (16 US.C. 1361-1384), Lacey Act (18 U.S.C. 42) and Convention on International Trade in Endangered Species of Wild Fauna and Flora, (d) DoD Directive 3216.1, (e) SECNAVINST 3900.38C, (f) NIH Guidelines for the Care and Use of Laboratory Animals and all other applicable regulatory compliance.

The use of non-human primates is prohibited and funds shall not be used toward non-human primate use unless the Recipient has received prior approval of its non-human primate efforts under this Cooperative Agreement by the Grants Officer.

The Recipient shall include this clause in all subawards.

4. ANIMAL WELFARE (DEC 1991)

(a) The Recipient shall register its research facility with the Secretary of Agriculture in accordance with 7 U.S.C. 2316 and 9 CFR Subpart C, and Section 2.30, and furnish evidence of such registration to the Grants Officer before beginning work under this Cooperative Agreement.

(b) The Recipient shall acquire animals only from dealers licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR Subpart A, Sections 2.1 through 2.11, or from sources that are exempt from licensing under those sections.

(c) The Recipient agrees that the care and use of animals will conform with the pertinent laws of the United States and regulations of the Department of Agriculture (see 7 U.S.C. 2131 *et. seq.* and 9 CFR Subchapter A, Parts 1 through 4).

(d) The Grants Officer may immediately suspend, in whole or in part, work and further payments under this Cooperative Agreement for failure to comply with the requirements of paragraphs (a) through (c) of this clause.

(1) The suspension will stay in effect until the Recipient complies with the requirements.

(2) Failure to complete corrective action within the time specified by the Grants Officer may result in termination of this cooperative agreement.

(e) The Recipient may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), for the region in which its research facility is located. The location of the appropriate APHIS regional office, as well as information concerning this program may be obtained by contacting the Senior Staff Officer, Animal Care Staff, USDA/APHIS, Federal Center Building, Hyattsville, MD 20782.

(f) The Recipient shall include this clause, including this paragraph (f), in all subawards involving research of live vertebrate animals.